K051458

Summary of Safety and Effectiveness Information
Capture PR-3 ANCA Test Kit

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I. Euro-Diagnostica AB
Per Albin Hanssons vag 41, Medeon
SE-205 12 Malmo Sweden
Contact person: Sten Gershagen
Telephone: 46-40-321100
Date of preparation: May 4, 2005

II. Description of Device: The Capture-PR3-ANCA test kit is an enzyme-linked immunosorbent assay (ELISA) for detection and semi-quantitation of IgG antibodies to proteinase 3 (PR3) in human sera. The assay is used to detect antibodies in a single serum specimen. The results of the assay are to be used as an aid to the diagnosis of Wegener's granulomatosis. The assay is intended for use in patients with signs and symptoms consistent with WG. It is not intended for screening a healthy population.The analysis should be performed by trained laboratory professionals.

The wells of the microtiter strips are coated with monoclonal antibody to proteinase 3 and subsequently proteinase 3. During the first incubation, specific antibodies in diluted serum, will bind to the antigen coating.

The wells are then washed to remove unbound antibodies and other components.
A conjugate of alkaline phosphatase-labeled antibodies to human IgG binds to the antibodies in the wells in this second incubation.

After a further washing step, detection of specific antibodies is obtained by incubation with substrate solution. The amount of bound antibodies correlates to the color intensity and is measured in terms of absorbance (optical density (OD)). The absorbance is then calculated against a calibrator curve and the results are given in arbitrary units.

III. Predicate Device

The Capture PR-3 ANCA test is substantially equivalent to the PR-3 ANCA ELISA Kit. Equivalence is demonstrated by the following comparative results:

Table 1. Clinical sensitivity and specificity. A total of 295 frozen retrospective sera with clinical characterisation were assayed. The following table summarises the results

Control and Disease groups	Total number	Negative < 20 units	Equivocal 21-30 units	Positive > 30 units
Blood donors:	120	120	0	0
WG:	50	2	0	48
MP:	34	17	2	15
SLE:	45	44	1	0
RA:	17	16	1	0
GBM:	29	26	0	3

WG = Wegener's granulomatosis, MP = microscopic polyangiitis
SLE = systemic lupus erythematosus RA = rheumatoid arthritis
GBM = glomerular basement membrane

Clinical sensitivity (Equivocal samples excluded from calculations)

WG = 48/50 = 96.0 % 95% CI = 86.3-99.5 %
MP = 15/32 = 46.9 % 95% CI = 29.1-65.3 %

Clinical specificity (Equivocal samples excluded from calculations)

GBM = 26/29 = 89.7 % 95% CI = 72.7-97.8 %
SLE = 44/44 = 100 % 95% CI = 92.0-100 %
RA = 16/16 = 100 % 95% CI = 79.4-100 %
Normal = 120/120 = 100 % 95% CI = 97.0-100 %

The 95% confidence interval (CI) was calculated using the exact method.

Table 2. Wielisa capture PR3-ANCA kit compared to IIF-ANCA. A total of 78 frozen retrospective sera from systemic vasculitis were assayed. The following table summarises the results.

	Wielisa Capture ELISA for PR3-ANCA			
IIF-ANCA	**Positive**	**Equivocal**	**Negative**	**Total**
c-ANCA	52	0	1	53
p-ANCA	1	1	13	15
Negative	10	0	0	10
Total	**63**	**1**	**14**	**78**

Table 3. Relative sensitivity and specificity of the Wielisa capture PR3-ANCA kit compared to an alternative ELISA. A total of 180 frozen retrospective sera were assayed. The following table summarises the results.

		Wielisa Capture ELISA for PR3-ANCA			
		Positive	**Equivocal**	**Negative**	**Total**
	Positive	40	0	0	40
Alternative	**Equivocal**	2	0	0	2
ELISA	**Negative**	2	2	134	138
	Total	44	2	134	180

Sera falling in the equivocal range were excluded from the following calculations.

Relative sensitivity	= 40/40 = 100%	95% CI = 91.2-100 %
Relative specificity	= 134/136 = 98.5 %	95% CI = 94.8-99.8 %
Relative Accuracy	= 174/176 = 98.9 %	95% CI = 96.0-99.9 %

The 95% confidence interval (CI) was calculated using the exact method.

Table 4. Batch to batch variation was determined by testing three different samples in duplicate. Results were obtained for five different batches.

Sample	**Mean value**	**SD**	**CV %**
PK	76 units	10	13
K1	45 units	3	7
K3	88 units	10	11

Table 5. Inter-assay precision was determined by testing four different samples in duplicate. Results were obtained for four different runs.

Sample	Mean value	SD	CV %
PK	85 units	5	6
K1	49 units	3	6
K2	77 units	5	7
K3	138 units	9	7

Table 6. Intra-assay precision was determined by testing two samples in 24 wells.

Sample	Mean value	SD	CV %
1	136	11	8
2	141	13	9

Table 7. Linearity. The values were determined for serial two-fold dilutions of three positive sera. The values were compared to log 2 of dilution by standard linear regression. The data indicates that the assay has a linear relationship with serum dilution.

Serum	neat	1:2	1:4	1:8	1:16	1:32	r
1	394	297	188	74	37	16	0.95
2	334	269	106	48			0.94
3	324	219	100	36	22	8	0.98

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Eurodiagnostica
c/o Mr. William L. Boteler Jr.
Immuno Probe, Inc.
1306 Bailes Lane, Suite F
Frederick, MD 21701

NOV 2 3 2005

Re: k051458
Trade/Device Name: Wieslab™ Cap PR-3 ANCA
Regulation Number: 21 CFR 866.5660
Regulation Name: Multiple autoantibodies immunological test system
Regulatory Class: Class II
Product Code: MOB
Dated: June 1, 2005
Received: June 2, 2005

Dear Mr. Boteler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K051458

Device Name: Wieslab™ Cap PR3-ANCA

Indications For Use: The Wieslab™ Cap PR3-ANCA is an enzyme-linked immunosorbent assay (ELISA) for detection and semi-quantitation of IgG antibodies to proteinase 3 (PR3) in human sera. The assay is used to detect antibodies in a single serum specimen. The results of the assay are to be used as an aid to the diagnosis of Wegener's granulomatosis. The assay is intended for use in patients with signs and symptoms consistent with WG. It is not intended for screening a healthy population.The analysis should be performed by trained laboratory professionals.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K051458